

Remarks

After entry of this Amendment, the pending claims are claims 1-53, with claims 27-53 withdrawn from consideration at this time. The Office Action dated November 21, 2003 has been carefully considered. Claims 1, 2, 14, 18 and 20 have been amended. No new matter has been added.

Reconsideration and allowance of the present application in view of the above amendments and the following remarks is respectfully requested.

In the Office Action dated November 21, 2003, the Examiner:

- withdrew claims 27 - 53 from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to nonelected inventions and species.
- rejected claims 1-17, 20 and 25 under 35 U.S.C. 112(2) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claim 1, "the spinal column," lacked a prior antecedent; in claim 2, "the intersection," lacked a prior antecedent; in claims 14 and 20, "the intermedullary canal of the donor bone," lacked a prior antecedent; and in claim 25, "the inner side region," lacked a prior antecedent.
- rejected claims 1, 2, 4, 8-11, 16 and 17 under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,888,227 to Cottle ("the Cottle patent");
- rejected claims 1, 2, 4, 5, 7-9 and 12-25 under 35 U.S.C. 102(e) as being anticipated by United States Patent No. 6,277,149 to Boyle et al. ("the Boyle patent");
- rejected claims 3, 6 and 26 under 35 U.S.C. 103(a) as unpatentable over the Boyle patent.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph**Independent Claims 1 and 23**

Independent claim 1 was rejected under 35 U.S.C. 112(2) as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claim 1, "the spinal column," lacked a prior

NYJD: 1509901.1

antecedent. Claim 1 has been amended to recite, *inter alia*, an implant for use in maintaining a desired distance between first and second bisected bone ends of a patient's spinal column. Applicants respectfully submit that there is sufficient antecedent basis for all terms in claim 1 and its dependent claims.

Dependent Claim 2

Dependent claim 2 was rejected under 35 U.S.C. 112(2) as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claim 2, "the intersection," lacked a prior antecedent. Claim 2 has been amended to recite, *inter alia*, the implant of claim 1 wherein the inner side region is angled with respect to each of the bone engaging portions. Applicants respectfully submit that there is sufficient antecedent basis for all terms in claim 2 and its dependent claims

Dependent Claim 14

Dependent claim 14 was rejected under 35 U.S.C. 112(2) as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claim 14, "the intermedullary canal of the donor bone," lacked prior antecedent. Claim 14 has been amended to recite, *inter alia*, the implant of claim 12 wherein the bone allograft material is obtained from a cross-section of a donor bone having an intermedullary canal, and wherein said inner surface of the implant is defined by the intermedullary canal of the donor bone. Applicants respectfully submit that there is sufficient antecedent basis for all terms in claim 14.

Dependent Claim 20

Dependent claim 20 was rejected under 35 U.S.C. 112(2) as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claim 20, "the intermedullary canal of the donor bone," lacked prior antecedent. Claim 20 has been amended to recite, *inter alia*, the implant of claim 19 wherein the bone allograft material is obtained from a cross-section of a donor bone having an intermedullary canal, and wherein said hollow portion is defined by the intermedullary canal of the donor bone. Applicants respectfully submit that there is sufficient antecedent basis for all terms in claim 20.

Dependent Claim 25

Dependent claim 25 was rejected under 35 U.S.C. 112(2) as being indefinite for failure to particularly point out and distinctly claim the subject matter which applicant regards as his invention. In particular, in claim 25, the Examiner stated that "inner side region," lacked a prior antecedent. Applicants note that the term "inner side region" has proper antecedent basis in line 3 of claim 18. Applicants have, however, amended claim 25 to recite, *inter alia*, the implant of claim 18 wherein the inner side region is angled with respect to each of the bone engaging portions to more distinctly claim the subject matter of the invention. Applicants respectfully submit that there is sufficient antecedent basis for all terms in claim 25, and its dependent claim.

Claim Rejections - 35 U.S.C. § 102Independent Claim 1The Cottle Patent

Independent claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by the Cottle patent. Independent claim 1 has been amended to recite, *inter alia*, an implant ... comprising ... a body portion having a length and configured to be insertable between first and second bisected bone ends of the spinous process of a single vertebra, the body portion having ... first and second ends comprising bone engaging portions, ... wherein said bone engaging portions are angled with respect to each other, and said implant is configured so as not to protrude into the spinal canal when inserted between the first and second bone ends.

Applicants respectfully submit that the Cottle patent does not disclose, teach or suggest all of the limitations of claim 1. Specifically, there is no disclosure, teaching or suggestion in the Cottle patent of an implant ... configured to be insertable between first and second bisected bone ends of the spinous process of a single vertebra. Rather, the spacer of the Cottle patent is an intervertebral implant, for insertion into the intervertebral space (*i.e.* the space between *adjacent* vertebra) to facilitate fusion of two vertebral bodies. (*See* Cottle patent at 1:11-12, 3:56, 4:13-15, 65-66). Thus, it is respectfully submitted that the Cottle patent does not disclose, teach, or suggest all of the limitations of independent claim 1. It is respectfully submitted that independent claim 1 is thus allowable over the Cottle patent. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested. With respect to claims 2-17 which depend from claim 1, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the

features of claim 1, they are also patentably distinguished over the Cottle patent for at least the same reasons as identified with respect to claim 1.

The Boyle patent

Independent claim 1 was rejected under 35 U.S.C. 102(e) as being anticipated by the Boyle patent. Independent claim 1 has been amended as indicated above in relation to the discussion of the Cottle patent. Applicants respectfully submit that the Boyle patent does not disclose, teach or suggest all of the limitations of claim 1. Specifically, there is no disclosure, teaching or suggestion in the Boyle patent of an implant ... configured to be insertable between first and second bisected bone ends of the spinous process of a single vertebra. Like the Cottle implant, the Boyle patent discloses an intervertebral implant 10, 12 for fusing *adjacent* vertebrae together to maintain proper spacing and lordosis between adjacent vertebrae (i.e. maintain the disc space). (See Boyle patent, 1:13, 18-22). The body has upper and lower surfaces 22 and 24 configured to engage vertebral *end plates* after implantation. (See *id.* at 4:5, 14-16).

It is respectfully submitted that independent claim 1 is thus allowable over the Boyle patent. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested. With respect to claims 2-17, which depend from claim 1, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 1, they are also patentably distinguished over the Boyle patent for at least the same reasons as identified with respect to claim 1.

Independent Claim 18

Independent claim 18 was rejected under 35 U.S.C. 102(b) as being anticipated by the Boyle patent. Independent claim 18 has been amended to recite, *inter alia*, an implant ... comprising a body portion ... configured to be insertable between first and second bone segments of a spinous process of a single vertebra, the body portion having first and second ends, at least one of the first and second ends comprising a bone engaging portion to engage at least one of the first and second bone segments, wherein ... at least one of the first and second bone engaging portions is comprised of a demineralized allograft material.

Applicants respectfully submit that the Boyle patent does not disclose, teach or suggest all of the limitations of claim 18. Specifically, there is no disclosure, teaching or

suggestion in the Boyle patent of an implant ... comprising a body portion ... configured to be insertable between first and second bone segments of a spinous process of a single vertebra. Like the Cottle implant, the Boyle patent discloses an intervertebral implant 10, 12 for fusing *adjacent* vertebrae together to maintain proper spacing and lordosis between adjacent vertebrae (i.e. maintain the disc space). (See Boyle patent, 1:13, 18-22). The body has upper and lower surfaces 22 and 24 configured to engage vertebral *end plates* after implantation. (See Boyle patent, 4:5, 14-16).

It is respectfully submitted that independent claim 18 is thus allowable over the Boyle patent. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested. With respect to claims 19-26, which depend from claim 18, applicants submit that because these claims define more particular aspects of the applicant's invention as well as including the features of claim 18, they are also patentably distinguished over the Boyle patent for at least the same reasons as identified with respect to claim 1.

Claim Rejections - 35 U.S.C. § 103

Dependent Claims 3, 6 and 26

The Boyle Patent

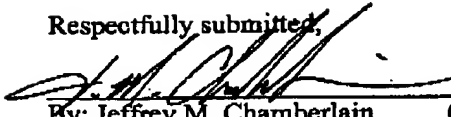
Dependent claims 3, 6 and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable in view of the Boyle patent. Claims 3 and 6 depend from claim 1, while claim 26 depends from claim 18. Because the features recited in independent claims 1 and 18 are not disclosed, taught or suggested by the Boyle patent, applicants respectfully submit that the dependent claims 3, 6 and 26 are patentable for at least the same reasons as identified with respect to claims 1 and 18, discussed above.

In light of applicants' amendments and remarks, a notice of allowance is respectfully requested. Should the examiner have any questions or concerns regarding the amendments, remarks or the above-identified application, then a telephonic interview with the undersigned is respectfully requested to discuss any such questions or concerns and to accelerate the allowance of the above-identified application.

Applicants estimate that no fee is required for this Amendment. Should any fees be deemed necessary, however, such fees should be charged to Jones Day Deposit Account No. 16-1150.

Respectfully submitted,

Date: February 23, 2004


By: Jeffrey M. Chamberlain

P55,044

(Reg. No.)

35,340

For: Brian M. Rothery

(Reg. No.)

JONES DAY

222 East 41st Street

New York, New York 10017

(212) 326-3939